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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte
JULIO C. PALMAZ, STEVEN R. BAILEY
CHRISTOPHER T. BOYLE, and CHRISTOPHER E. BANAS

Appeal 2011-002092
Application 09/707,685
Technology Center 3700

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims 39-53 and 67-74, directed to a method of manufacturing an endoluminal stent. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

This is the second time Appellants have appealed the Examiner's final rejection of the claims in this case. In the previous appeal (Appeal No. 2008-1316, decided September 29, 2008 ("Decision")), we affirmed the Examiner's rejection of identical claims as anticipated by Whitcher (Publication No. US 2003/0018381 A1, published January 23, 2003).

Appellants subsequently filed a Request for Continued Examination, and submitted new evidence and arguments, which form the basis for Appellants' present appeal of the Examiner's continued final rejection of the claims.

Claims 39-53 and 67-74 again stand rejected under 35 U.S.C. § 102(e) as anticipated by Whitcher.

As the claims have not been argued separately, and therefore stand or fall together, we select claim 39 as representative of the claimed subject matter for the purpose of deciding all issues raised by this appeal. 37 C.F.R. § 41.37(c)(1)(vii). Claim 39 is as follows:

39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to minimize formation of chemical and intra- and intergranular precipitates in the bulk material;

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film; and

c. removing the endoluminal stent from the generally cylindrical substrate.

ISSUE

Appellants contend that Whitcher "does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material" (App. Br. 7).

The Examiner finds that Appellants' "disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation . . .) as *the means for minimizing precipitates* and other material properties" (Ans. 5), and that Whitcher "dislose[s] use of the same vacuum deposition processes . . . and the use of the same materials used by the appellant . . . and discloses [that] such processes control material properties" (*id.*). Therefore, the Examiner contends, "inherently Whitcher is controlling and minimizing material properties such as granular precipitates" (*id.* at 6).

The issue raised by this appeal is whether the preponderance of the evidence of record supports the Examiner's finding that Whitcher's vacuum deposition process inherently minimizes formation of chemical and intra- and inter-granular precipitates in the bulk material of the deposited film.

FINDINGS OF FACT

1. The present invention is directed to an endoluminal stent with "a luminal surface thereof which presents less obstruction to longitudinal shear forces during fluid flow across the luminal surface . . . while maximizing fatigue life and corrosion resistance" (Spec. 1: 7-12).

2. "The inventive stent . . . is preferably made of a bulk material having controlled heterogeneities on the luminal surface thereof" (Spec. 10: 22-24). "[H]eterogeneities are controlled by fabricating the bulk material of

the stent to have defined grain sizes, chemical and intra and intergranular precipitates" (Spec. 10: 26-28).

3. According to the Specification, "physical properties, including . . . elasticity, tensile strength, mechanical properties, hardness, bulk and/or surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates" are encompassed by the term "material properties" (Spec. 10: 13-16).

4. The Specification teaches that "the foregoing properties are achieved by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and nano-fabrication vacuum coating arts . . . . The preferred deposition methodologies include ion-beam assisted evaporative deposition and sputtering techniques" (Spec. 11: 11-15).

5. "In ion beam-assisted evaporative deposition it is preferable to employ dual and simultaneous thermal electron beam evaporation with simultaneous ion bombardment of the substrate using an inert gas, such as argon, xenon, nitrogen or neon . . . [which] serves to reduce void content . . . [and] allows the mechanical properties of that deposited material to be similar to the bulk material properties" (Spec. 11: 15-22).

6. Alternate deposition processes which may be employed to form the stent . . . are cathodic arc, laser ablation, and direct ion beam deposition" (Spec. 11: 28-30).

7. According to the Specification, "[v]apor deposition of the inventive endoluminal stent . . . significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" and "the need to

control precipitates for mechanical properties is eliminated" (Spec. 14: 19-25).

8. There are no working examples in the present Specification, but the Specification indicates that "[m]aterials to make the inventive stents . . . include the following: elemental titanium, . . . nickel, tantalum, zirconium, . . . and alloys thereof, such as zirconium-titanium-tantalum alloys, nitinol, and stainless steel" (Spec. 12: 5-10). In addition, the Specification teaches that

> the chamber pressure, the deposition pressure and the partial pressure of the process gases are controlled to optimize deposition of the desired species onto the substrate. As is known in the . . . vacuum coating arts, both the reactive and non-reactive gases are controlled and the inert or non-reactive gaseous species introduced into the deposition chamber are typically argon and nitrogen

(Spec. 12: 11-16). "The deposited material may[ ]be deposited either as a uniform solid film onto the substrate, or patterned" (Spec. 12: 18-19).

9. In addition, the present Specification incorporates U.S. Patent Application No. 09/443,929, now U.S. Patent No. 6,379,383 B1 (Palmaz et al., issued April 30, 2002, the "'383 patent") by reference (Spec. 10: 24-26). According to the present Specification, the '383 patent describes a process whereby "heterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes . . . [and] chemical and intra and intergranular precipitates" (*id.* at 10: 26-28).

10. The '383 patent does not specifically mention "precipitates," but does teach that "conventional stents have marked surface and subsurface heterogeneity resulting from manufacturing processes . . . [which] results in formation of surface and subsurface inclusions with chemical composition

and, therefore reactivity different from the bulk material" ('383 patent, col. 2, ll. 21-27). "Unpredictable distribution of inclusions such as those mentioned above provide an unpredictable and uncontrolled heterogeneous surface available for interaction with plasma proteins and cells" (*id.*at col. 2, ll. 30-34).

11. The '383 patent teaches that a metal stent with controlled heterogeneities can be achieved "by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and nano-fabrication vacuum coating arts . . . includ[ing] ion-beam assisted evaporative deposition and sputtering techniques" (*id.* at col. 5, ll. 55-61).

12. Working Examples 1-4 of the '383 patent disclose specific vacuum deposition processes, including sputtering and ion beam-assisted evaporative deposition ('383 patent, cols. 7-8).

13. Whitcher teaches that "conventional processes used to produce patterned stents often start with wire, tube or sheet materials" and typical processing steps include winding, welding, heat treating, stamping, cutting, etching, expanding, and/or rolling the material to create the final device (Whitcher ¶ 3). According to Whitcher, "[m]ost of the manufacturing steps associated with these conventional methods introduce defects into the metallic structure of the formed device" (Whitcher ¶ 4), for example, localized deformation and surface flaws (*id.*).

14. According to Whitcher,

> Some defects in the formed device may be reduced by techniques, such as annealing, but these techniques often impart other undesirable effects. For instance, annealing often requires high temperature treatment of a metallic device to recrystallize its microstructure to reduce grain size . . . . Such a high temperature treatment can often impart physical deformation of

> the device due to thermal heating and cooling steps or due to the change in the microstructure itself.

(Whitcher ¶ 5.)

15. Whitcher describes a method of manufacturing medical devices, including radially expandable intraluminal stents with interconnected longitudinal and circumferential structural elements (Whitcher ¶ 45, Figs. 1, 2), "having improved mechanical properties" (Whitcher ¶ 8). According to Whitcher, "the difficulties associated with conventional medical devices and the methods used to form such medical devices" can be overcome "[b]y using vapor deposition techniques" to "accurately and precisely control[ ]" "the composition, thickness, surface roughness, and microstructure" of the medical devices (Whitcher ¶ 28).

16. According to Whitcher, "[t]he medical devices formed by the process of . . . [vapor deposition] are tailored to have desired compositions, mechanical properties, and geometries" (Whitcher ¶ 28). Further, a metallic layer "can be formed to have a range of crystalline morphologies, including a monocrystalline or a nanocrystalline morphology" using vapor deposition techniques (Whitcher ¶ 48).

17. Whitcher teaches that "[e]xamples of useful vapor deposition processes . . . include physical vapor deposition processes such as evaporation and sputtering. Direct and assisted ion beam deposition, and chemical vapor deposition are also useful" (Whitcher ¶ 34).

18. Whitcher teaches that

> The material deposited as the metallic layer [on a mandrel] . . . is any suitable material for use in medical device applications, such as . . . nitinol, stainless steel, titanium, [etc.] . . . . The vapor deposition of these materials results in a deposited metallic layer . . . having a fine, equiaxed

> microstructure which may be precisely established as a function of process parameters. These microstructures in turn affect mechanical properties such as strength and corrosion resistance

(Whitcher ¶ 62). "After release from the mandrel . . . the metallic layer . . . either serves as a stent or as the basis for forming a stent" (Whitcher ¶ 54).

19. In Example 1 of Whitcher, an equiaxed, nanocrystalline, "patterned nitinol stent is formed according to the following processing steps" (Whitcher ¶¶ 66, 67):

> A steel wire mandrel measuring about 10 mm in diameter and 30 mm in length is placed in a vacuum chamber . . . . Also mounted in the chamber is a nitinol source target comprising about 55.9 wt % nickel and the balance essentially titanium. The chamber is then evacuated to a pressure of less than 10^{-6} torr. Argon is introduced into the chamber at a flow rate . . . producing an operating pressure of about 10 millitorr. A plasma is then generated in the chamber by ion bombardment of the nitinol target, resulting in nitinol deposition onto the wire mandrel. Sputter deposition is continued until the thickness of the deposited nitinol layer is about 0.25 mm, after which the coated mandrel is removed from the chamber.
>
> The coated mandrel is cut at both ends to a length of about 20 mm. A pattern is formed in the coated mandrel by machining oval-shaped holes through the thickness thereof. The deposited nitinol layer is removed from the mandrel by dissolving the mandrel in hydrochloric acid thus yielding a functional nitinol stent with a fine, equiaxed and nanocrystalline microstructure. . . . A grain size of the nanocrystalline structure is measured to be less than 10 nanometers by this technique.

(Whitcher ¶¶ 66, 67). Examples 2-5 describe additional vapor deposition processes that produce a nitinol layer in nanocrystalline form.

20. Hollister[1] teaches that bulk nanocrystalline materials and coatings "are generally made up of crystals the size of which are measured in micrometers" (Hollister 6).

21. Pelton[2] discusses the formation of precipitates in nitinol (nickel titanium alloy) wire manufactured by drawing the material through a series of dies, followed by continuous strand annealing (Pelton 108, col. 1). The precipitates are described essentially as "localized shifts of composition," e.g., congregation of nickel atoms, occurring at various temperatures during the annealing process (*id.* at 114, col. 2).

DISCUSSION

The Examiner rejected claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by Whitcher.

Whitcher describes a method of manufacturing a metallic, radially expandable endoluminal stent with interconnecting longitudinal and circumferential structural elements (FFs 15, 16). The Examiner acknowledges that "Whitcher does not explicitly recite [minimizing] granular precipitates" (Ans. 5), but finds that Whitcher's method inherently minimizes formation of chemical and intra- and intergranular precipitates in

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[1] P. Hollister et al., *Nanocrystalline Materials*, no. 4, Cientifica, October 2003 (at nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf) (submitted as Exhibit A with Appellants' Appeal Brief, and previously submitted with the Request for Continued Examination dated August 17, 2009).

[2] A.R. Pelton et al., *Optimisation of processing and properties of medical grade Nitinol wire*, 9 Min. Invas. Ther. & Allied Technol. 107-118 (2000) (submitted as Exhibit B with Appellants' Appeal Brief, and previously submitted with the Request for Continued Examination dated August 17, 2009).

the bulk material, because Whitcher discloses "the same vacuum deposition processes (sputtering, ion beam deposition . . .) and the use of the same materials used by the appellant . . . and discloses such processes control material properties" (*id.*). Further, the Examiner finds that "Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties" (*id.* at 6), by "selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which appellant has disclosed to be the method of minimizing precipitates)" (*id.*).

In affirming the Examiner's rejection in our previous Decision in this case, we noted that

> [t]he present Specification indicates that the material properties of a crystalline metal film, including "surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates . . . are achieved by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and nano-fabrication vacuum coating arts" . . . preferably "ion-beam assisted evaporative deposition and sputtering techniques"

(Decision 9-10). We also noted that the Specification "indicates that the choice of vapor deposition to manufacture metallic stents 'significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material'" (*id.* at 10).

We were not persuaded that the Examiner's rejection was in error by any of the arguments presented at that time for reasons of record (*see* pages 10-12 of the Decision), which we will not reiterate here. Nor are we persuaded by Appellants' new arguments and evidence in support of their

renewed contention that Whitcher "does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material" (App. Br. 7).

Specifically, Appellants contend that US Patent No. 6,379,383 B1, which is incorporated by reference in the present specification (FF9), "discloses several working examples of sputtering a stainless steel film with a circumferential deposition source, whereby specific vacuum deposition conditions control the surface properties of the deposited metal film . . . [such as] controlled heterogeneities in grain size, material composition and surface topography" (App. Br. 13). Appellants contend that "[s]uch vacuum deposition conditions disclosed in the '383 patent are remarkably different than Whitcher" (*id.*), and "the Examiner inappropriately ignores these specific vacuum deposition process parameters" (*id.*).

This argument is not persuasive. As noted by the Examiner, the '383 patent does not specifically mention "precipitates" (Ans. 14), although that doesn't mean that the processes disclosed therein don't inherently minimize precipitates. In any case, the disclosure of the '383 patent is similar to the present Specification's in many respects. For example, the '383 patent teaches that "conventional stents have marked surface and subsurface heterogeneity resulting from manufacturing processes" ('383 patent, col. 2, ll. 21-22), which "provide an unpredictable and uncontrolled heterogeneous surface available for interaction with plasma proteins and cells" (*id.*at col. 2, ll. 32-34) (FF10).

In order to avoid these problems, the '383 patent, like the present Specification, teaches that a stent with controlled heterogeneities can be achieved "by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and nano-fabrication vacuum coating arts . . . includ[ing] ion-beam assisted evaporative deposition and sputtering techniques" (*id.* at col. 5, ll. 55-61) (*compare* FF4 and FF11).

As for the working examples in the '383 patent, we agree with the Examiner that the "[t]he process conditions disclosed in the incorporated application are only one example of [vapor deposition] process conditions and they are not disclosed to reduce precipitates" (Ans. 14).

Appellants also cite Hollister (*see* FF20) as evidence that "[t]he term 'nanocrystalline' . . . is generally understood to simply be nano-scale polycrystalline structures" (App. Br. 8). Appellants further contend that the term "'monocrystalline' is generally understood to mean 'formed of a single crystal-unit, and so all elements have identical crystallographic orientation . . . and overgrow as one unit" (*id.*). Appellants cite Pelton (*see* FF21) as evidence that the term "precipitate" is widely known to those skilled in the metallurgical arts to mean "reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in the formation of the reaction products outside the solid solution, *i.e.*, outside the metal crystalline structure" (*id.*).

Based on this evidence, Appellants contend that "one of ordinary skill in the art would not equate nanocystalline or monocrystalline with precipitates, as precipitates themselves are outside the metal crystalline structure" (*id.* at 9). Thus, Appellants contend that the fact that Whitcher

"describes nano-scale crystal structures as desirable to enhance mechanical properties of the medical device . . . does not speak to minimized precipitation formation" (*id.* at 8).[3]

This argument is not persuasive. The Examiner's position is not based on a finding that one of ordinary skill in the art would equate nanocrystalline or monocrystalline films with precipitates, or rather a lack of precipitates. As discussed above, the Examiner's position is that Whitcher discloses forming nanocrystalline (and monocrystalline) metal layers using "the same vacuum deposition processes (sputtering, ion beam deposition . . .) and . . . the same materials used by the appellant" (Ans. 5). We agree with the Examiner that the preponderance of the evidence of record indicates that it is the vacuum deposition process itself that minimizes the formation of precipitates in or on the deposited film.

Appellants also argue that "Pelton is related to cold-work and heat treatment of nitinol and shows that precipitates of nitinol that include $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$" form in the worked product (App. Br. 8). Appellants further contend that

> Precipitates are formed during the increased thermal conditions of vacuum deposition techniques, i.e. heating a source material to a temperature to cause vaporization thereof for evaporization, or ionizing metals that collide with gas atoms and dislodge source material as in sputtering deposition, or using high energy beam of metals by ionizing a source material as in ion beam assisted deposition.

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[3] Appellants also contend that Whitcher's monocrystalline materials "are drawn filaments and are not, therefore, vacuum deposited onto a cylindrical substrate to form a tubular film structure with minimized precipitates" (App. Br. 8). However, Whitcher additionally discloses forming a monocrystalline layer over a cylindrical mandrel by vapor deposition (Whitcher ¶ 48; FF16).

(*Id.*).

This argument is not persuasive. Pelton describes precipitates which form when a solid solution of nickel and titanium ions undergoes annealing, but does not discuss vapor deposition of nitinol, or any other alloy or elemental metal. Appellants have provided no evidence that the thermal conditions of vapor deposition produce precipitates, in the source material, the vapor phase, or the deposited film. Attorney argument is not evidence. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Finally, to the extent Appellants contend that "any inherency threshold cannot be overcome by using or relying on the teachings of Applicant's disclosure for minimizing precipitates" (App. Br. 10), and the Examiner is improperly using Appellants' Specification as prior art (*id.*), we disagree. The Examiner quite properly looked to the Specification to determine the processes and conditions responsible for minimizing formation of chemical and intra- and intergranular precipitates, for purposes of comparison with the processes and conditions of the prior art.

Having considered the respective positions of Appellants and the Examiner, we find that the Examiner has established a prima facie case of anticipation of the claimed invention by a preponderance of the evidence, which Appellants have not overcome by argument or evidence. We therefore affirm the Examiner's rejection of the claims as anticipated by Whitcher.

SUMMARY

The rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by Whitcher is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

<u>AFFIRMED</u>

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